stryker
Medical

K113598

DEC 20 2011

510(k) Summary

Manufacturer and Submitter

Company Name:	Stryker Medical
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Contact Person:	Renata Sila
Date Summary Prepared:	October 31, 2011

Device

Trade/Device Name:	Power-LOAD™ Cot Fastener System
Common/Usual Name:	Accessory to Wheeled Stretcher
Classification Name:	Wheeled Stretcher
Regulation Number:	21 CFR 880.6910
Product Code:	FPO
Classification Panel:	General Hospital
Classification:	Class II

Predicate Device:
IRSG I-Mover for Beds, International Retail Services Group LLC (K072598)

Device Description
The Power-LOAD system secures an ambulance cot within an emergency transport vehicle/ambulance. Power-LOAD includes a trolley that attaches to the cot during the loading and unloading process, a transfer assembly that facilitates linear motion of the trolley and an anchor assembly that attaches to a floor plate mounted to the vehicle floor. When a Power-LOAD-compatible cot is securely attached to the trolley, a battery-powered hydraulic system assists the operators in lifting, lowering and loading and unloading a cot. When the cot is secured in the transport position, Power-LOAD can interface with and inductively charge compatible model 6506 Power-PRO™ XT and 6516 Power-PRO™ IT ambulance cots. In the event of power loss, the system remains functional for securing the cot within the vehicle. In this case, loading and unloading of the cot would be achieved manually, as is standard practice today. There will be three cots compatible with Power-LOAD, Power-PRO XT, Power-PRO IT and Performance-PRO XT.

Intended Use/Indications for Use

The Power-LOAD™ cot fastening system (model 6390) is intended to assist with loading and unloading of a compatible wheeled stretcher (ambulance cot) to and from a transport vehicle and to secure the ambulance cot during transport. The device has a maximum safe working load of 870 lbs, which includes the weight of the ambulance cot, patient, and equipment attached to the cot (i.e. oxygen bottles, monitors, and/or pumps). The intended users of the device will be trained professionals including: emergency medical service and medical care center personnel, as well as medical first responders, service technicians and installers. The expected service life of the product is 7 years.

Substantial Equivalence Analysis

The Power-LOAD™ Cot Fastener is similar in technology and intended use to the IRSG I-Mover for Beds, International Retail Services Group LLC (K072598), which is used to assist healthcare personnel in the movement of a wheeled stretcher, either patient-laden or non-laden, in a healthcare setting.

Similarities include the main function of moving a wheeled stretcher and assisting medical personnel with patient transfer. Both devices are accessories to a wheeled stretcher. Differences include the compatibility of Power-LOAD solely with Stryker wheeled stretchers, the additional capability to lift the stretcher by Power-LOAD, which is affixed to an ambulance vehicle, and the capability of the predicate to move hospital beds as well as wheeled stretchers.

Verification and validation of design and performance for Power-LOAD demonstrates that these technology differences do not adversely affect safety and effectiveness of the device when used as labeled, as the device has been fully tested for use and performance to demonstrate its safe and effective use.

Non-Clinical Performance Summary

Stryker Medical has verified and validated that the Power-LOAD™ meets its functional, performance, safety and efficacy specifications and requirements. Extensive software testing and mechanical testing of individual components and of the final device has been conducted. Power-LOAD has successfully passed electrical safety and electromagnetic compatibility testing and complies with International Standards. Power-LOAD has received passing test reports for IEC 60601-1, 60601-1-2 and FCC Parts 15 and 18. Physical and mechanical testing has been performed on individual components and on the system, including abuse testing to simulate worst-use scenarios. Test results demonstrated that both the individual units and system meet performance requirements. User needs studies were conducted to ensure that user needs are met.

Power-LOAD has been designed and evaluated according to the following Domestic and International Standards:

- IEC 60601-1: 1988 + A1: 1991 + A2: 1995
- IEC 60601-1-2 Edition 3:2007-03
- IEC 60601-2-38: 1996 + A1: 1999
- IEC 60601-1-4: 1996 + A1: 1999
- ANSI/AAMI/IEC 62304: 2006
- AAMI SW68: 2001
- ISO 14971: 2007
- ISO 13485: 2003
- BS EN 1789: 2007
- CFR 47 FCC Part 15, 2011, Subpart C, Section 15:225
- CFR 47 FCC Part 18, 2011

The extensive performance testing that has been conducted on the individual components and on the finished system demonstrates that the Power-LOAD™ Cot Fastener is safe and effective, meets its intended use, and is substantially equivalent to the predicate device.

Conclusion

In summary, Stryker Medical, a division of Stryker Corporation, has demonstrated that Power-LOAD™ Cot Fastener is as safe and effective as similar devices currently on the market, and concludes that Power-LOAD™ is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stryker Medical
C/O Bhavesh V. Sheth
Responsible Third Party Official
InterTek Testing Services
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

DEC 2 0 2011

Re: K113598
Trade/Device Name: Power-LOAD™ Cot Fastener System
Regulation Number: 21 CFR 880.6910
Regulation Name: Wheeled Stretcher
Regulatory Class: II
Product Code: FPO
Dated: December 2, 2011
Received: December 5, 2011

Dear Bhavesh V. Sheth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113598

Device Name: Power-LOAD™ Cot Fastener System

Indications For Use:

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Prescription Use _____ AND/OR Over-The-Counter Use __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/20/2011

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113598